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Tween(R) 80 [9005-65-6] MW 172840

Synonyms: Polyoxyethylene Sorbitan Monooleate; Tween 80; Sorethytan (20) mono-oleate; Polyethylene oxide sorbitan mono-oleate; Sorbitan mono-oleate polyoxyethylene; Sorlate; Olothorb; Polyoxyethylene (20) sorbitan monooleate; Sorbitan, mono-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs., (Z)-; (x)-sorbitan mono-9-octadecenoate poly(oxy-1,2-ethanediyl) derivs; sorbitan, monooleate polyoxyethylene deriv.; armotan pmo-20; capmul poe-o; drewmulse poe-smo; emsorb 6900; glycosperse 0-20; glycosperse 0-20 veg; glycosperse 0-20x; liposorb 0-20; polysorbate 80 b.p.c.; polysorbate 80; protasorb o-20; sorbimacrogol oleate 300; polyoxyethylene (5) sorbitan monooleate; Sorbitan, mono-9-octadecanoate, poly(oxy-1,2-ethanediyl) derivs., (Z)-; POE (5) sorbitan monooleate; POE (20) sorbitan monooleate; POE(6) Sorbitan Monooleate; PEG-6 Sorbitan Oleate; POLYOXYETHYLENESORBITAN MONOOLEATE (TWEEN 80);

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ACX Number X1001237-2

Melting Point (°C)

Boiling Point (°C)

Refractive Index

Evaporation Rate

Flash Point (°C)

DOT Number

Comments

CAS RN 9005-65-6

Density 1.064

Vapor Density

Vapor Pressure

Water Solubility 5-10 g/100 mL at 23 C

EPA Code

RTECS WG2932500

Yellow liquid. Hydrophilic emulsifier; solubilizer; dispersant; water soluble.

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FINANCE



[Code of Federal Regulations]
[Title 21, Volume 3, Parts 170 to 199]
[Revised as of April 1, 1999]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR172.840]

[Page 83-84]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 172--FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

Subpart I--Multipurpose Additives

Sec. 172.840 Polysorbate 80.

The food additive polysorbate 80 (polyoxyethylene (20) sorbitan monooleate), which is a mixture of polyoxyethylene ethers of mixed partial oleic acid esters of sorbitol anhydrides and related compounds, may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reacting oleic acid (usually containing associated fatty acids) with sorbitol to yield a product with a maximum acid number of 7.5 and a maximum water content of 0.5 percent, which is then reacted with ethylene oxide.

(b) The food additive meets the following specifications:

Saponification number 45-55.

Acid number 0-2.

Hydroxyl number 65-80.

Oxyethylene content 65 percent-69.5 percent.

(c) The additive is used or intended for use as follows:

(1) An emulsifier in ice cream, frozen custard, ice milk, fruit sherbet, and nonstandardized frozen desserts, when used alone or in combination with polysorbate 65 whereby the maximum amount of the additives, alone or in combination, does not exceed 0.1 percent of the finished frozen dessert.

(2) In yeast-defoamer formulations whereby the maximum amount of the additive does not exceed 4 percent of the finished yeast defoamer and the maximum amount of the additive in the yeast from such use does not exceed 4 parts per million.

(3) As a solubilizing and dispersing agent in pickles and pickle products, whereby the maximum amount of the additive does not exceed 500 parts per million.

(4) As a solubilizing and dispersing agent in:

(i) Vitamin-mineral preparations containing calcium caseinate in the absence of fat-soluble vitamins, whereby the maximum intake of polysorbate 80 shall not exceed 175 milligrams from the recommended daily dose of the preparations.

(ii) Fat-soluble vitamins in vitamin and vitamin-mineral preparations containing no calcium caseinate, whereby the maximum intake of polysorbate 80 shall not exceed 300 milligrams from the recommended daily dose of the preparations.

(iii) In vitamin-mineral preparations containing both calcium caseinate and fat-soluble vitamins, whereby the maximum intake of

polysorbate 80 shall

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not exceed 475 milligrams from the recommended daily dose of the preparations.

(5) As a surfactant in the production of coarse crystal sodium chloride whereby the maximum amount of the additive in the finished sodium chloride does not exceed 10 parts per million.

(6) In special dietary foods, as an emulsifier for edible fats and oils, with directions for use which provide for the ingestion of not more than 360 milligrams of polysorbate 80 per day.

(7) As a solubilizing and dispersing agent for dill oil in canned spiced green beans, not to exceed 30 parts per million.

(8) As an emulsifier, alone or in combination with polysorbate 60, in shortenings and edible oils intended for use in foods as follows, when standards of identity established under section 401 of the act do not preclude such use:

(i) It is used alone in an amount not to exceed 1 percent of the weight of the finished shortening or oil.

(ii) It is used with polysorbate 60 in any combination providing no more than 1 percent of polysorbate 80 and no more than 1 percent of polysorbate 60, provided that the total combination does not exceed 1 percent of the finished shortening or oil.

(iii) The 1-percent limitation specified in paragraph (c)(8) (i) and (ii) of this section may be exceeded in premix concentrates of shortening or edible oil if the labeling complies with the requirements of paragraph (d) of this section.

(9) As an emulsifier in whipped edible oil topping with or without one or a combination of the following:

(i) Sorbitan monostearate;

(ii) Polysorbate 60;

(iii) Polysorbate 65;

whereby the maximum amount of the additive or additives used does not exceed 0.4 percent of the weight of the finished whipped edible oil topping.

(10) It is used as a wetting agent in scald water for poultry defeathering, followed by potable water rinse. The concentration of the additive in the scald water does not exceed 0.0175 percent.

(11) As a dispersing agent in gelatin desserts and in gelatin dessert mixes, whereby the amount of the additive does not exceed 0.082 percent on a dry-weight basis.

(12) As an adjuvant added to herbicide use and plant-growth regulator use dilutions by a grower or applicator prior to application of such dilutions to the growing crop. Residues resulting from such use are exempt from the requirement of a tolerance. When so used or intended for use, the additive shall be exempt from the requirements of paragraph (d)(1) of this section.

(13) As a defoaming agent in the preparation of the creaming mixture for cottage cheese and lowfat cottage cheese, as identified in Secs. 133.128 and 133.131 of this chapter, respectively, whereby the amount of the additive does not exceed .008 percent by weight of the finished products.

(14) As a surfactant and wetting agent for natural and artificial colors for use in barbecue sauce where the level of the additive does not exceed 0.005 percent by weight of the barbecue sauce.

(d) To assure safe use of the additive, in addition to the other

information required by the Act:

(1) The label of the additive and any intermediate premixes shall bear:

(i) The name of the additive.

(ii) A statement of the concentration or strength of the additive in any intermediate premixes.

(2) The label or labeling shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

[42 FR 14491, Mar. 15, 1977, as amended at 43 FR 2871, Jan. 20, 1978; 45 FR 58835, Sept. 5, 1980; 46 FR 8466, Jan. 27, 1981]

- (1) Crooks; US 4572915 A 1986 CA
- (2) Muller; US 4719239 A 1988 CA
- (3) Schmidt; US 4727109 A 1988 CA
- (4) Story; US 4944949 A 1990 CA